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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,649	06/10/2005	Michael Huenerbein	3223-104	3729

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EXAMINER
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ROY, ANURADHA

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/538,649	<b>Applicant(s)</b> HUENERBEIN, MICHAEL	
	<b>Examiner</b> Anuradha Roy	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/10/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 & 6-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Gatto (US Publication No. 2003/0181823).

Regarding claim 1, Gatto discloses an optical biopsy instrument (Figure 1), comprising

- (a) a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one lateral opening (region of 34 & 35), and
- (b) an endoscope (12) which is axially movable inside [0036] the cannula (14).

In regards to claim 2, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that the at least one lateral opening (region of 34 & 35) of the cannula (12) has at least in parts a cutting region (35) at its area being directed towards the distal end and/or at its area being directed towards the proximal end.

Regarding claim 3, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that the cutting region (35) is formed by a ground edge of the circumference of the at least one lateral opening (region of 35 & 34) or by a tothing of the circumference or by both measures concurrently.

In regards to claim 4, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that the at least one lateral opening (region of 34 & 35) has a substantially round, oval, elliptic or rectangular configuration.

Regarding claim 6, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that an external diameter of the endoscope (12) substantially corresponds to an internal diameter of the cannula (14) or is slightly smaller than this [0036].

With regard to claim 7, Gatto discloses an optical biopsy instrument (Figure 1), characterized in that an external diameter of the cannula is 1.2 mm at most [0012].

Regarding claim 8, Gatto discloses an optical biopsy instrument (Figure 1) according to claim 1, characterized in that the endoscope (12) is a rigid endoscope or a flexible glass-fibre endoscope.

In regards to claim 9, Gatto discloses a use of an optical biopsy instrument (Figure 1) for endoscopy and/or biopsy of duct systems having small diameters, in particular of milk ducts of mammary glands [0019].

Regarding claim 10, Gatto discloses a method for sampling tissue samples in duct systems, wherein

- (a) an optical biopsy instrument (Figure 1), comprising a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one lateral opening (region of 35 & 34), and an endoscope (12) which is axially movable inside the cannula (14) is introduced, under endoscopic monitoring, into the duct up to a biopsy site, [0036]
- (b) the tissue sample ( ) is brought through the free lying opening (region of 34 & 35) into an interior of the cannula (14), and
- (c) the tissue sample is capable of being separated from the rest of the tissue by moving forward the endoscope (12) across the lateral opening (28) and/or by retracting the endoscope (12), until the lateral opening (region of 34 & 35) is closed.

Regarding claim 11, Gatto discloses a method for sampling tissue samples in duct systems, wherein

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- (a) an optical biopsy instrument (Figure 1), comprising a substantially cylindrical cannula (14) inherently having a proximal end and a distal end, said cannula (14) having at least one lateral opening (region of 35 & 34), and an endoscope (12) which is axially movable inside the cannula (14) is introduced, under endoscopic monitoring, into the duct, until the lateral opening (region of 34 & 35) comes to lie over a biopsy site,
- (b) the tissue sample is brought through the free lying opening (38) into an interior of the cannula (14), and
- (c) the tissue sample is separated from the rest of the tissue by moving the cannula (14) having a free lying lateral opening (region of 35 & 34) together with the fixed endoscope (12) forward or backward, thereby manually exerting a gentle pressure against the tissue sample.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto in view of Fleener et al. (US Publication No. 2004/0127767).

Gatto discloses the aforementioned elements. However, Gatto does not disclose an optical biopsy instrument, which the cannula is closed at its distal end by a wall, in particular by a transparent wall. However, Fleener et al. does disclose a optical biopsy device, whereing the cannula is closed at its distal end by a wall, in particular a transparent wall [0013]. It would have been obvious to one having ordinary skill in the art at the time the invention in view of Fleener et al. to incorporate a transparent distal wall with Gatto in order to allow an imaging device to view the tissue disposed adjacent to the outside surface of the housing.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR

  
MAX F. HINDENBURG  
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